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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,367	11/08/2001	David H. McDaniel	509582000221	5657

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EXAMINER	
FARAH, AHMED M	
ART UNIT	**PAPER NUMBER**
3739	8

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/986,367	Applicant(s) Dr. David McDaniel
	Examiner Ahmed M. Farah	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 19, 2003*

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 8, and 10-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 8, and 10-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's written description fails to teach that the intensity of the stimulating energy '<u>causes no skin ablation</u>' as presently claimed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 10-16 are again rejected under 35 U.S.C. 102(e) as being anticipated by Tankovich et al. U.S. Pat. No. 6,050,990.

Tankovich et al. disclose methods and devices for applying laser light to the skin of a patient, including methods for removing hair, for synchronizing hair growth, and for stimulating hair growth (see the abstract).

As to claims 10, 12, 15 and 16 , their methods for stimulating hair growth comprise the steps of: selecting at least one photomodulating agent **14** having an average diameter enabling the agent to penetrate the hair duct (see Fig. 17), the agent selected from a group consisting a dye and other photomodulating agents (Col. 9, lines 38-44); applying the agent to a skin section containing hair (see Fig. 22); and exposing the skin and the agent to electromagnetic radiation having a wavelength of about 1064 nm (see Col. 11, line 3).

As to claim 11, the electromagnetic radiation source is selected from the group consisting of an ultrasound radiation emitter, a laser (Col. 10, line 27), and a flash-lamp (Fig. 35 and Col. 8, lines 48-64).

As to claim 13, the photomodulating agent has an absorption characteristic including an absorption maxima at a wavelength equal to the wavelength of radiation source. See Col. 9, lines 35-38. As to claim 14, their device would provide at least one of the claimed features.

Response to Arguments

5. Applicant's arguments filed on May 19, 2003 have been fully considered but they are not persuasive. As to the device claims 10 and 16, the applicant argues that "Tankovich **only** teaches

the use of lasers" and therefore does not anticipate his invention (the limitations amended claims 10 and 16), which requires *'a **multichromatic** light source.'*

In response to this argument, Tankovich teaches that the source for providing the treatment energy comprises a laser **or** a flash-lamp (Col. 8, line 49). In this Office Action, flash-lamp' is defined as a gaseous-discharge lamp, which produces **multichromatic** flashes of light of short duration and high intensity. Therefore, since Tankovich teaches the use of non-laser multichromatic light source to provide the treatment energy, the Examiner maintains his prior rejection.

6. Applicant's arguments with respect to claims 1 and 8 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the 'Laser Hair Care 4000' brochure.

The brochure teaches that the use of 'cold-beam' laser technology or Low Level Laser Therapy (LLLT) to treat 'individuals suffering from thinning hair and hair loss (i.e., to stimulate hair growth)' has been known in the medical art since the 1980's. However, although the brochure teaches the use of 'Cold-beam' laser, it does not particularly provide the operating wavelength range of the treatment laser ('Laser Hair Care 4000 model, developed in 1996).

As to the limitation that the intensity of treatment energy causes no 'skin ablation" in amended claim 1 lacks sufficient support in the specification and therefore is not given a patentable weight.

Hair regrowth with Cell-wave(R) Therapy (Copyright © 1996, Published by Cell-wave Therapy Australia), discloses an alternative hair growth/regrowth apparatus and technique in which '**Cold-beam**" laser irradiation is employed to stimulate hair growth. In this publication, the 'Cold-beam' laser is described as having a wavelength of 630 nm and above.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Laser Hair Care's brochure to use a cold-beam laser having a wavelength of between 390 and 1600 nm (i.e., 630 nm and above) to increase blood flow to the scalp and hair follicle in order to stimulate hair growth as presently claimed.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima

facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). See MPEP § 2144.05.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can

be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; and the fax number for After Final is (703) 872-9303.

JOHN MULCAHY
PRIMARY EXAMINER

A. M. Farah

Patent Examiner (Art Unit 3739)

August 4, 2003.

Linda C. M. Dvorak

Supervisory Patent Examiner